

REMARKS

Upon entry of the above amendment, claims 1-8, 10 and 12-14 will be pending in the captioned application. The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendment is respectfully requested.

1. Objection to claim 9

The Official Action states that claim 9 is objected to. However, claim 9 is not pending in the present application because it was canceled without prejudice to or disclaimer of the subject matter contained therein in the Preliminary Amendment filed on February 25, 2005.

Accordingly, applicants respectfully request that the Examiner withdraw this objection.

2. Rejection of claim 1 under 35 U.S.C. §112, 2nd paragraph

The Official Action states that claim 1 is rejected under 35 U.S.C. §112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Official Action states, in relevant part, the following:

The claim recites for the definition of R6 to be Aryl-1-4C-alkylcarbonyl "beduetet".

RESPONSE

Applicants respectfully submit that claim 1 has been amended to delete the term "bedeutet" as suggested by the Examiner. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 1.

2. Rejection of Claims 1-10, 11 and 12 under 35 U.S.C. §112, 1st paragraph

The Official Action states that claims 1-10, 11 and 12 are rejected under 35 U.S.C. §112, 1st paragraph for lack of enablement. In particular, the Official Action states that "the specification, while being enabling for 12 compounds to have some PDE3 and PDE4 inhibiting activity, does not reasonably provide enablement for the compounds to be able to treat illnesses and pharmaceutical use."

RESPONSE

Applicants respectfully traverse this rejection.

First, applicants respectfully remind the Examiner that claims 9 and 11 are not pending in this application, rendering the rejection of this claim moot. In particular, applicants note that claims 9 and 11 are not pending in the present

application because they were canceled without prejudice to or disclaimer of the subject matter contained therein in the Preliminary Amendment filed on February 25, 2005.

Regarding the rejection of the remaining claims, applicants point out to the Examiner that the rejected claims are clearly enabled by the instant specification because applicant has demonstrated a nexus between 1) the effectiveness of the compounds of formula I to inhibit phosphodiesterases (PDE) 3 and 4 and 2) the common knowledge in the art that PDE inhibition is useful in treating diverse inflammatory diseases including airway disorders and dermatoses. The present specification contains references to publications demonstrating this relationship on page 27.

Further, the instant specification contains data on page 29 which clearly demonstrates that the presently claimed compounds inhibit PDE3 and PDE4. Further, it is well known in the art that the inhibition of PDE3 and PDE4 and treatment of diverse inflammatory diseases, as presently claimed, are related.

In this regard, the specification contains numerous references to publications demonstrating the relationship between inhibition of PDE3 and PDE4 and the treatment of various inflammatory diseases. See pages 23-26. In addition to the

references explicitly outlined in the present specification, applicant has submitted herewith an Information Disclosure Statement citing two (2) references which each demonstrate the relationship between PDE3 and PDE4 inhibition and the treatment of various inflammatory diseases. The relevant portions of the two IDS are briefly discussed below.

The Montana et al. reference provides clear enabling support for the use of a PDE3/4 inhibitor in the treatment of airway disorders, Crohn's disease and dermatoses. In this regard, Montana et al. teach in Table 1 (pg. 42) that the PDE4 Inhibitor CDC-801 by Celgene can be used in the treatment of Crohn's disease; Cilomilast can be used in the treatment of asthma and COPD; Roflumilast can be used in the treatment of asthma and COPD; BAY19-8004 can be used in the treatment of asthma and COPD; and CIPAMPHYLLINE can be used in the treatment of Atopic Dermatitis.

Similarly, the Souness et al. reference provides clear enabling support for the use of a PDE3/4 inhibitor in the treatment of rheumatoid arthritis and dermatoses. In particular, Table 6 (pg. 144) shows that Piclamilast (RP73401) is used to treat the inflammatory disease arthritis and Atizoram (CP-80633) is used to treat the inflammatory disease atopic

dermatitis. Further, on page 146, in section 8, entitled "Potential of PDE4 inhibitors in arthritis", Souness et al. teach that "RA patients treated with piclamilast...in a small clinical study showed a positive trend in respect of serum concentrations of IL-6 and CRP although the corresponding levels of TNF-alpha and IL-1 were unaffected. Patients reported some improvement in symptoms."

In regards to the dermatoses indication, Souness et al. further teach on page 148, section 10, entitled "Potential of PDE4 inhibitors in dermatological disorders", that PDE4 inhibiting "compounds have been evaluated with some success in patients with dermatological complaints such as atopic dermatitis (AD) and psoriasis." Souness et al., in section 8.2, also teach "Ro 20-1724 and CP-80633 demonstrate some efficacy when applied topically to AD patients. For example, atizoram, when applied as a topical ointment (0.5%) over 28 days to affected areas in 20 AD patients, demonstrated efficacy with significant reductions in all inflammatory parameters measured."

Accordingly, a person of ordinary skill in the art would be enabled by the instant specification, combined with the common knowledge in the art, to practice the presently claimed invention.

Further, applicants respectfully point out that if the enablement rejection of the Examiner is upheld, it would mean that an inventor of an innovative new drug would have to wait to file her patent application until human clinical trials were performed. Such a conclusion is obviously incorrect. A reasonable correlation between a compound's activity and its asserted use, as demonstrated by applicant with the data and the literature references filed herewith, is clearly enough to properly demonstrate enablement of the presently claimed methods.

Accordingly, claims 1-10 and 11-12 comply with the requirements of 35 U.S.C. §112, 1st paragraph. As such, applicant respectfully requests that the Examiner reconsider and withdraw this rejection of claim 1-8, 10, and 12.

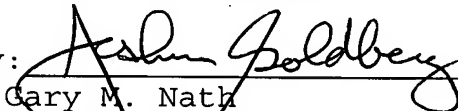
CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the objection of claim 9 and the rejection of claims 1-8, 10 and 12-14 and to allow all of the claims pending in this application to proceed to grant.

If the Examiner has any questions or wishes to discuss this matter, he is welcomed to telephone the undersigned attorney.

Respectfully submitted,

THE NATH LAW GROUP

By: 
Gary M. Nath
Registration No. 26,965
Joshua B. Goldberg
Registration No. 44,126
Sheldon M. McGee
Registration No. 50,454
Customer No. 34375

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
(703)-548-6284
GMN/SMM\ROA.doc